

AMENDMENTS TO THE CLAIMS

Claim 1 (Previously presented): A composition for the treatment of post-surgical articular or incisional pain or discomfort consisting essentially of an aqueous dispersion of insoluble non-crosslinked type I fibrillar atelopeptide collagen and an anesthetic; wherein the composition is formulated to release an effective amount of the anesthetic from the collagen for at least 48 hours, wherein the collagen and the anesthetic are in a ratio of from about 0.5:1 to about 10:1, and wherein the melting temperature of the composition is from about 42 °C to about 46 °C.

Claim 2 (Previously presented): The composition of claim 1, wherein the anesthetic is soluble in the dispersion.

Claim 3 (Previously presented): The composition of claim 1, wherein the composition is formulated to release an effective amount of the anesthetic from the collagen for at least 72 hours.

Claim 4 (Previously presented): The composition of claim 1, wherein the collagen and the anesthetic are in a ratio of from about 1:1 to about 5:1.

Claim 5 (Previously presented): The composition of claim 4, wherein the collagen and the anesthetic are in a ratio of about 1:1.

Claim 6 (Original): The composition of claim 1, wherein the collagen consists essentially of at least 95% Type I non-crosslinked fibrillar atelopeptide collagen.

Claim 7 (Previously presented): The composition of claim 1, wherein the collagen is less than 5% Type III collagen.

Claim 8 (Cancelled).

Claim 9 (Previously presented): The composition of claim 1, wherein the anesthetic is bupivacaine, lidocaine, procaine, procainamide, tetracaine, mepivacaine, or etidocaine.

Claim 10 (Original): The composition of claim 1, wherein the collagen is human collagen or bovine dermal collagen.

Claims 11-17 (Cancelled).

Claim 18 (Previously presented): The composition of claim 1, wherein the collagen concentration is from about 3 mg/ml to about 100 mg/ml.

Claim 19 (Previously presented): The composition of claim 18, wherein the collagen concentration is about 65 mg/ml.

Claim 20 (Previously presented): The composition of claim 18, wherein the collagen concentration is from about 16 mg/ml to about 28 mg/ml.

Claim 21 (Previously presented): The composition of claim 1, wherein the anesthetic concentration is about 4-30 mg/ml.

Claim 22 (Previously presented): The composition of claim 21, wherein the anesthetic concentration is from about 4 mg/ml to about 10 mg/ml.

Claim 23 (Previously presented): The composition of claim 1, wherein a total amount of anesthetic released is from about 5 mg to 1g.

Claim 24 (Previously presented): The composition of claim 1, wherein the effective amount of anesthetic released is from about 2-15 mg per day.

Claim 25 (Previously presented): The composition of claim 24, wherein the effective amount of anesthetic released is about 10 mg per day.

Claim 26 (Previously presented): The composition of claim 1, further comprising one or more pharmaceutically acceptable excipient(s).

Claim 27 (Previously presented): A composition for the treatment of post-surgical articular or incisional pain or discomfort consisting essentially of an aqueous dispersion of insoluble non-crosslinked type I fibrillar atelopeptide collagen and bupivacaine; wherein the composition is formulated to release an effective amount of bupivacaine from the collagen for at least 48 hours, and wherein the collagen and bupivacaine are in a ratio of from about 0.5:1 to about 10:1, and wherein the melting temperature of the composition is from about 42 °C to about 46 °C.

Claim 28 (Previously presented): The composition of claim 27, wherein the bupivacaine is soluble in the dispersion.

Claim 29 (Currently Amended): The composition of claim 27, wherein the composition is formulated to release [[and]] an effective amount of bupivacaine from the collagen for at least 72 hours.

Claim 30 (Previously presented): The composition of claim 27, wherein the collagen and bupivacaine are in a ratio of from about 1:1 to about 5:1.

Claim 31 (Previously presented): The composition of claim 30, wherein the collagen and bupivacaine are in a ratio of from about 3:1 to about 4.7:1.

Claim 32 (Original): The composition of claim 27, wherein the collagen consists essentially of at least 95% Type I non-crosslinked fibrillar atelopeptide collagen.

Claim 33 (Previously presented): The composition of claim 27, wherein the collagen is less than 5% Type III collagen.

Claim 34 (Previously presented): The composition of claim 27, wherein the collagen concentration is from about 10 mg/ml to about 100 mg/ml.

Claim 35 (Previously presented): The composition of claim 34, wherein the collagen concentration is about 65 mg/ml.

Claim 36 (Previously presented): The composition of claim 34, wherein the collagen concentration is from about 16 mg/ml to about 28 mg/ml.

Claim 37 (Previously presented): The composition of claim 27, wherein the bupivacaine concentration is about 4-30 mg/ml.

Claim 38 (Previously presented): The composition of claim 37, wherein the bupivacaine is at a concentration is from about 4 mg/ml to about 10 mg/ml.

Claim 39 (Previously presented): The composition of claim 27, wherein a total amount of bupivacaine released is from 5 mg to 1g.

Claim 40 (Previously presented): The composition of claim 27, wherein the effective amount of bupivacaine released is about 2-15 mg per day.

Claim 41 (Previously presented): The composition of claim 27, further comprising one or more pharmaceutically acceptable excipients.

Claim 42 (Currently amended): A method for the treatment of post-surgical pain or discomfort in a joint(s) comprising the step of intra-articularly administering to a joint(s) in a ~~patent~~ patient a composition consisting essentially of an aqueous dispersion of insoluble non-crosslinked Type I fibrillar atelopeptide collagen and an anesthetic; wherein the composition is formulated to release an effective amount of the anesthetic from the collagen for at least 48 hours, wherein the collagen and the anesthetic are in a ratio of from about 0.5:1 to about 10:1, wherein the melting temperature of the composition is from about 42 °C to about 46 °C, and wherein the composition is administered before, during or after a surgical procedure.

Claim 43 (Original): The method of claim 42, wherein the joint is a knee, shoulder, ankle, hip, wrist, elbow or temporomandibular joint.

Claim 44 (Original): The method of claim 43, wherein the joint is a knee.

Claim 45 (Original): The method of claim 42, wherein the patient is a human or veterinary patient.

Claim 46 (Original): The method of claim 45, wherein the patient is a human.

Claim 47 (Original): The method of claim 42, wherein the composition is administered before the surgical procedure.

Claim 48 (Original): The method of claim 47, wherein the method further comprises the step of at least one additional administration of the composition during or after the surgical procedure.

Claim 49 (Original): The method of claim 42, wherein the composition is administered during the surgical procedure.

Claim 50 (Original): The method of claim 42, wherein the composition is administered after the surgical procedure.

Claim 51 (Original): The method of claim 42, wherein the composition is administered via a catheter.

Claim 52 (Original): The method of claim 42, wherein the surgical procedure is arthroscopy, arthrotomy, implantation of chondrocytes, implantation of cartilage, partial joint arthroplasty or total joint arthroplasty.

Claim 53 (Original): The method of claim 42, wherein the surgical procedure is used in the treatment of a condition selected from the group consisting of meniscal injury, anterior cruciate ligament injury, rotator cuff injury, carpal tunnel syndrome, synovitis, chondromalacia, patellar tendon rupture, tibial tubercle fracture, loose bodies of bone or cartilage, osteochondritis dissecans, adhesive capsulitis, impingement syndrome, shoulder dislocation, Dupuytren's syndrome, scaphoid

fracture, stenosing tenosynovitis, lateral facet syndrome, anterior patello-femoral pain syndrome, lateral pressure syndrome, malalignment syndrome, and maltracking syndrome.

Claim 54 (Previously presented): The method of claim 53, wherein the condition is not a degenerative articular process.

Claim 55 (Previously presented): The method of claim 42, wherein the composition is formulated to release an effective amount of the anesthetic from the collagen for at least 72 hours.

Claim 56 (Previously presented): The method of claim 42, wherein the collagen and the anesthetic are in a ratio of from about 1:1 to about 5:1.

Claim 57 (Original): The method of claim 42, wherein the collagen consists essentially of at least 95% Type I non-crosslinked fibrillar atelopeptide collagen.

Claim 58 (Original): The method of claim 42, wherein the collagen is less than 5% Type III collagen.

Claim 59 (Cancelled).

Claim 60 (Previously presented): The method of claim 42, wherein the anesthetic is bupivacaine, lidocaine, procaine, procainamide, tetracaine, mepivacaine, or etidocaine.

Claims 61-67 (Cancelled).

Claim 68 (Previously presented): The method of claim 42, wherein the collagen concentration is from about 3 mg/ml to about 100 mg/ml.

Claim 69 (Previously presented): The method of claim 42, wherein the anesthetic concentration is about 4-30 mg/ml.

Claim 70 (Previously presented): The method of claim 69, wherein the anesthetic concentration is from about 4 mg/ml to about 10 mg/ml.

Claim 71 (Previously presented): The method of claim 42, wherein a total amount of anesthetic released is from about 5 mg to 1g.

Claim 72 (Previously presented): The method of claim 42, wherein the effective amount of anesthetic released is from about 2-15 mg per day.

Claim 73 (Previously presented): The method of claim 72, wherein the effective amount of anesthetic released is about 10 mg per day.

Claim 74 (Original): The method of claim 42, wherein the amount of composition administered is greater than 2 mL.

Claim 75 (Original): The method of claim 42, wherein the composition further includes one or more pharmaceutically acceptable excipient(s).

Claim 76 (Previously presented): A method for the treatment of post-surgical pain or discomfort associated with one or more incisions comprising the step of administering to a patient's incision(s) a composition consisting essentially of an aqueous dispersion of insoluble non-crosslinked type I fibrillar atelopeptide collagen and an anesthetic; wherein the composition is formulated to release an effective amount of the anesthetic from the collagen for at least 48 hours, wherein the collagen and the anesthetic are in a ratio of from about 0.5:1 to about 10:1, wherein the melting temperature of the composition is from about 42 °C to about 46 °C, and wherein the composition is administered before, during or after a surgical procedure.

Claim 77 (Original): The method of claim 76, wherein the surgical procedure is an abdominal, spinal or breast operation.

Claim 78 (Original): The method of claim 77, wherein the abdominal operation is a cesarean birth, hernia repair, or hysterectomy.

Claim 79 (Original): The method of claim 76, wherein the composition is administered via injection.

Claim 80 (Original): The method of claim 76, wherein the patient is a human or veterinary patient.

Claim 81 (Original): The method of claim 80, wherein the patient is a human.

Claim 82 (Original): The method of claim 76, wherein the composition is administered before the surgical procedure.

Claim 83 (Original): The method of claim 82, wherein the method further comprises the step of at least one additional administration of the composition during or after the surgical procedure.

Claim 84 (Original): The method of claim 76, wherein the composition is administered during the surgical procedure.

Claim 85 (Original): The method of claim 76, wherein the composition is administered after the surgical procedure.

Claim 86 (Original): The method of claim 76, wherein the composition is administered via a catheter.

Claim 87 (Cancelled).

Claim 88 (Previously presented): The method of claim 76, wherein the anesthetic is bupivacaine.

Claim 89 (Previously presented): A method for the treatment of post-surgical pain or discomfort in a joint(s) comprising the step of intra-articularly administering to a joint(s) in a patient a composition consisting essentially of an aqueous dispersion of insoluble non-crosslinked Type I fibrillar atelopeptide collagen and bupivacaine, wherein the composition is formulated to release an effective amount of bupivacaine from the collagen for at least 48 hours, and wherein the collagen and bupivacaine are in a ratio of from about 0.5:1 to about 10:1, wherein the melting temperature of the composition is from about 42 °C to about 46 °C, and wherein the composition is administered before, during or after a surgical procedure.

Claim 90 (Original): The method of claim 89, wherein the joint is a knee, shoulder, ankle, hip, wrist, elbow or temporomandibular joint.

Claim 91 (Original): The method of claim 90, wherein the joint is a knee.

Claim 92 (Original): The method of claim 89, wherein the patient is a human or veterinary patient.

Claim 93 (Original): The method of claim 92, wherein the patient is a human.

Claim 94 (Original): The method of claim 89, wherein the composition is administered before the surgical procedure.

Claim 95 (Original): The method of claim 94, wherein the method further comprises the step of at least one additional administration of the composition during or after the surgical procedure.

Claim 96 (Original): The method of claim 89, wherein the composition is administered during the surgical procedure.

Claim 97 (Original): The method of claim 89, wherein the composition is administered after the surgical procedure.

Claim 98 (Original): The method of claim 89, wherein the composition is administered via a catheter.

Claim 99 (Original): The method of claim 89, wherein the surgical procedure is arthroscopy, arthrotomy, implantation of chondrocytes, implantation of cartilage, partial joint arthroplasty or total joint arthroplasty.

Claim 100 (Original): The method of claim 89, wherein the surgical procedure is used in the treatment of a condition selected from the group consisting of meniscal injury, anterior cruciate ligament injury, rotator cuff injury, carpal tunnel syndrome, synovitis, chondromalacia, patellar tendon rupture, tibial tubercle fracture, loose bodies of bone or cartilage, osteochondritis dissecans, adhesive capsulitis, impingement syndrome, shoulder dislocation, Dupuytren's syndrome, scaphoid fracture, stenosing tenosynovitis, lateral facet syndrome, anterior patello-femoral pain syndrome, lateral pressure syndrome, malalignment syndrome, and maltracking syndrome.

Claim 101 (Original): The method of claim 89, wherein the composition is formulated to release an effective amount of bupivacaine from the collagen for at least 72 hours.

Claim 102 (Previously presented): The method of claim 89, wherein the collagen and bupivacaine are in a ratio of from about 1:1 to about 5:1.

Claim 103 (Original): The method of claim 89, wherein the collagen consists essentially of at least 95% Type I non-crosslinked fibrillar atelopeptide collagen.

Claim 104 (Original): The method of claim 89, wherein the collagen is less than 5% Type III collagen.

Claim 105 (Original): The method of claim 89, wherein the collagen is human collagen or bovine dermal collagen.

Claim 106 (Previously presented): The method of claim 89, wherein the collagen concentration is from about 3 mg/ml to about 100 mg/ml.

Claim 107 (Previously presented): The method of claim 89, wherein the bupivacaine concentration is about 4-30 mg/ml.

Claim 108 (Previously presented): The method of claim 107, wherein the bupivacaine concentration is from about 4 mg/ml to about 10 mg/ml.

Claim 109 (Previously presented): The method of claim 89, wherein a total amount of bupivacaine released is from about 5 mg to 1g.

Claim 110 (Previously presented): The method of claim 89, wherein the effective amount of bupivacaine released is from about 2-15 mg per day.

Claim 111 (Previously presented): The method of claim 110, wherein the effective amount of bupivacaine released is about 10 mg per day.

Claim 112 (Previously presented): The method of claim 89, wherein the amount of composition administered is greater than 2 mL.

Claim 113 (Previously presented): The method of claim 89, wherein the composition further includes one or more pharmaceutically acceptable excipient(s).

Claim 114 (Cancelled).

Claim 115 (Previously presented): The composition of claim 1, wherein the melting temperature of the composition is about 45 °C.

Claim 116 (Previously presented): The composition of claim 27, wherein the melting temperature of the composition is about 45 °C.